

## Exhibit “D”

## Letters to the Editor

demonstrating what the problem is and how extensive the problem may be. There is the perception, rightly or wrongly in the B-reading community, that some B readers have "never" seen a negative film and some have "never" seen a positive film for pneumoconiosis. The bias of B readers who regularly read for plaintiffs' attorneys may be of equal, less, or greater magnitude than the bias of B readers who regularly read for defense attorneys. The study by Gitlin and colleagues was "conducted for" and presumably funded by defense attorneys. Although the individual members of the consultant B readers panel were unaware of "the study sponsors, the possible litigants, the previous or initial readers, and the individuals whose examinations they interpreted," no mention is made of whether or not they regularly read radiographs for defense attorneys. Insufficient information is provided on the consultant B readers to permit determining for whom they normally read radiographs.

My second concern about Gitlin and colleagues' paper is that the presentation of the data they collected (1) overstates the differences between the initial and the consultants' radiographic readings. First, one would expect all the initial readings to be abnormal. Only abnormal readings were selected for the study. There would be no case filed and no radiograph submitted to the consultant B readers if the initial reading were normal. Therefore, it makes no sense to state that the high degree of positive results in the initial recordings is inconsistent with the prevalence of such findings in published cohorts of asbestos-exposed workers. The study population was not a cohort of asbestos-exposed workers, it was a cohort of positive radiographs.

Second, there are clearly outliers among the consultants. Gitlin et al use the average of all the consultants' results, rather than eliminating the outliers. For example, in their Table 1b, the average percentage of radiographs rated as good by the consultants was 33.4 even though two of the consultants' percentages included in the average were appreciably lower 4.5% and 15.2%. A second example occurs in the authors' Table 2d, where in only 39 instances did all 6 consultants say that a radiograph was completely negative when the initial B reader said that the radiograph was not completely negative. Actually, for 143 radiographs at least 3 of the 6 consultants agreed that the

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### To The Editor:

As a non-radiologist B reader I do not profess to be a regular reader of *Academic Radiology*, but a colleague pointed out to me the interesting article by Gitlin et al (1) and the accompanying editorial (2) on comparison of B readers' interpretations of chest radiographs for pneumoconiosis.

Something may be rotten in the state of Denmark, but unfortunately the article by Gitlin et al (1) falls short of

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initial reading was not completely negative. However, the authors calculated their odds ratios of the differences between the initial and consultant B readers on the premise that only if all 6 consultants read the film as not completely negative was the radiograph considered not completely negative by the consultants. The odds ratios of the difference would be appreciably less if the 143 radiographs that were read as not completely negative by at least 3 of the 6 consultants were considered to be not completely negative.

Even with the re-calculation of the statistics in a more equitable manner, differences, though not as striking, will remain between the initial and the consultants' readings. The process of selecting B readers for this type of study, and how the data are analyzed so that outliers are eliminated, are of the utmost importance if we are to address the problem of how B readings are used in litigation and which individual truly has an abnormal radiograph.

As a B reader and epidemiologist for 20 years, who has mainly (> 90% of the time) read chest radiographs for research studies and governmental programs, I share the concern expressed in the editorial on whether something is rotten or not and the need to have independent studies performed to assess this issue.

#### Author's disclosure:

The author has received fees from both plaintiffs and defense attorneys as an expert witness and for performing independent medical examinations.

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2. Janover ML, and Berlin L. "B" Readers' radiographic interpretation in asbestos litigation: is something rotten in the courtroom? *Acad Radiol* 2004; 11:841-842.

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#### To the Editor:

In their article on the comparison of B readers' interpretation of chest radiographs for asbestos-related changes (1), Gillin and co-authors present the results of a multi-reader comparison of radiographic readings for pneumoconiosis, and conclude that "there is not support in the literature on X-ray studies of workers exposed to asbestos and other mineral dusts for the high level of positive findings recorded by the initial readers in this report."

We take issue with many of the points in their article, but would like here to focus on the methods used in the study they discuss. The study, done at Johns Hopkins Medical Center, consisted of a re-reading of chest radiographs of plaintiffs in asbestos litigation, originally read by doctors (B readers) selected by plaintiffs' attorneys. The re-reading was done by a panel of B readers selected by the study's authors; the study was done at the behest of attorneys for defendants in asbestos litigation. We ask the following questions:

1. How were the "consultant" readers selected by the study's authors? There is no basis to judge the independence of the consultant B readers. The paper states that the consultant readers were "compensated for their participation." Was this by defense attor-

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neys? If so, does that not create the appearance, if not the reality, of conflict on the part of the consultants who re-read the radiographs?

2. How was the set of 551 cases chosen? Since these films were of individuals who had retained an attorney in asbestos litigation, we can presume that all of the films had been interpreted as showing some asbestos-related disease. This is confirmed by Table 2a in Gitlin and colleagues' article. There are thousands of such cases filed each year. If these 551 cases were ones consecutively received by a specific asbestos trust fund, they could be considered representative. The authors have an obligation to describe the method used for choosing the case sample for the study, rather than stating that they have no idea how the sample was chosen. In addition, the reason for the reduction of the initial sample of 551 to the final analytic sample of 492 is not clear.
3. Because this is a selected series of positive radiographs submitted for compensation, it is not appropriate to conclude that "there is not support in the literature on X-ray studies of workers exposed to asbestos and other mineral dusts for the high level of positive findings recorded by the initial readers in this report." The sample tells us nothing about a rate of positive findings among all exposed workers screened, or even the proportion read as positive by this select group of initial B readers. The study simply does not have any denominator data upon which to base such a conclusion.
4. Although the consultant readers disagreed with the initial readers, they disagreed among themselves as well. For many of the comparisons made in this paper, the agreement among the consultants was at best fair (Table). In making the kind of comparisons made in this study, some amount of agreement is expected by chance alone. The  $\kappa$  statistic adjusts for this chance agreement. Kappa is positive when agreement is better than chance (a value of 1 equals complete agreement), is zero when agreement equals what would be expected by chance, and is negative when agreement is worse than would be expected by chance. Landis and Koch (2) have suggested that  $\kappa$  values greater than about 0.75 represent excellent agreement, values between 0.40 and 0.75 indicate fair to good agreement, and values below about 0.40 represent poor agreement beyond chance.

Table  
Kappa Statistic for Agreement among Consultant Readers

Parameter	Kappa Statistic for Agreement among Consultant Readers	Kappa Descriptor
Film quality	0.10 (0.08-0.12)	Poor
Is film completely negative?	0.43 (0.40-0.46)	Fair
Any parenchymal abnormalities consistent with pneumoconiosis?	0.31 (0.28-0.33)	Poor
Small opacities 1/0 or greater?	0.19 (0.18-0.21)	Poor
Any pleural abnormalities consistent with pneumoconiosis?	0.49 (0.47-0.52)	Fair

In the study described by Gitlin and colleagues, there is a clear difference between the initial reader and the consultant readers in the overall classification of films as completely normal or not. However, additional statistical analyses showed poor to fair agreement among the "consultant" readers for chest-radiograph film quality, any parenchymal abnormality, and profusion category. Adding the initial reader to the measure of agreement did not change the value of the  $\kappa$  statistic for film quality, and only changed it slightly for the finding of whether or not the film was completely negative and for the finding of pleural abnormalities consistent with pneumoconiosis. In essence, the initial reader was in the same ballpark as the consultant readers for many of the important parameters evaluated. Prior literature documents that there is a great deal of variability in classification of radiographs using the International Labour Office (ILO)-1980 system. But one cannot really conclude from this analysis that the consultant readers were any more accurate than the initial readers. An analysis of each reader in comparison to the other five consultant readers would have been illustrative (3), to show the range of agreement among the consultant readers as well as with the initial reader.

5. The ILO classification system was not designed to be used as a diagnostic test, and the diagnosis of asbestosis requires more than a radiographic interpretation. The American Thoracic Society recently issued a new set of guidelines for the clinical diagnosis of non-malignant lung disease related to asbestos (4). We agree with Gitlin and colleagues that classification based on a single radiograph is subject to observer variability, and should not be used as the only criterion for a di-



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agnosis of asbestos-related disease. It is important for the physician diagnosing asbestosis not to rely on chest radiographs alone, and in fact the Association of Occupational and Environmental Clinics has stated that such an act is unethical (5). There are additional and medically necessary steps to reach a diagnosis of asbestosis. However, we cannot support the conclusions of Gitlin and colleagues' study because of the potential bias in the selection of the study sample, the potential bias on the part of the consultant readers, and the clear high rate of variability among the consultant readers.

## Authors' disclosure statement:

The authors of this letter have done medical-legal work in the area of asbestos-related disease in the form of medical reports and testimony for patients seen in their clinical practice, and in some cases for individuals not examined. The major portion of this work has been for plaintiffs' attorneys. For this work we have received consultation fees. Our research in the area of asbestos-related disease has not been funded by attorneys, nor have other relevant activities, such as testimony before the U.S. Congress or the drafting of published guidelines for the diagnosis and treatment of asbestosis.

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## From:

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## To The Editor:

Gitlin and colleagues have revisited the problem of variability in the interpretation of radiographs obtained for the purpose of detecting asbestos-related abnormalities (1). The problem that they address has persisted for too long, and is worth re-examining so long as it persists.

The documented findings are expected. First, the authors used a methodology that is not designed to understand the problem, beginning with films interpreted by B-readers retained by plaintiffs' attorneys. Second, very substantial differences in reader behavior were inferred between readers in our much larger study two decades ago. This earlier study was not conducted in the context of legal proceedings, and relied on very large numbers of randomly distributed packets of radiographs obtained on behalf of the U.S. Navy (and its substantial industrial operations, including shipyards). Despite the large numbers of films for each reader and the absence of a legal setting, it was clear that epidemics could appear and disappear depending on the choice of reader (2).

The impact of B-reader behavior was substantial then, and not unidirectional. For 23 high-volume B-readers, Navy data abnormalities  $\geq 1/0$  ranged from 0.05% to 10.93% (median: 1.71%), and from 0.02% to 7.55% for  $\geq 1/1$ , encompassing several orders of magnitude (4). While "over-reading" is emphasized in the article by Gitlin and colleagues and the accompanying editorial by Janower and Berlin (3), the failure to find existing disease is generally regarded as the most serious problem in medical surveillance efforts. Because the normative film in most samples will be normal, an "over-reader" may appear more culpable than an "under-reader" in the types of statistical analyses that both we and Gitlin and colleagues applied. Both over-reading and under-reading are important problems; deciding which is the more culpable error is a matter of perspective. Quality assurance is a good for the goose as well as for the gander.

It has been clear for two decades that the social utility of the B-reading program as currently configured is problematic. The assertion that the International Labour Office system was "designed for research" is merely a failure to address the social problem. That failure in turn affects the health beliefs of our patients. The B-reading process is also referred to in U.S. Occupational Safety and Health Administration law (1910.1001). It is time to stop pretending that the testing examination alone provides sufficient quality assurance to address the needs of exposed populations. The solution attributed to me by Gitlin and colleagues (1), of multiple readings, is likely to be an

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improvement; if used alone, however, it will lead to under-reading, for several statistical reasons. The substantial differences among the expert panel for positive films in the article by Gitlin and colleagues illustrate one aspect of the problem. Requiring positive agreement among multiple readers is no more logical than the same requirement for negative agreement: without additional quality assurance, such a step would be insufficient and punitive. If the goal is to standardize readings, several approaches could improve quality assurance. Ultimately, all of these approaches amount to a concerted effort to reduce the number of readers to a group that will read similarly. An "asbestos board," with experts who undergo ongoing quality assurance testing and are also retained for continued normative behavior and dropped for non-normative behavior, is probably the simplest approach (4). There is no "gold standard," but we can achieve consistency. The barriers are political, not statistical.

Because the mixed messages from certified interpreters affect our patients' health beliefs, and because health beliefs affect behavior at many levels, the data presented are sufficient justification for considering the current system. The goal is not to choose a winning side—taking sides is part of what has gotten us to where we are today. Rather, the goal is to provide quality assurance. Some means to ensure consistent behavior, most likely in a small number of readers who undergo continual, random, voluntary quality assurance testing processes, is the socially useful solution. Getting there will require a "C-reading" from a planning committee that demonstrates competence, compassion, courage, and compromise.

## Author's disclosure

Dr. Ducatman is not a B-reader and does not receive personal payment for testifying concerning his patients. Dr. Ducatman is an internist and occupational physician, and some of his patients are seen for reasons related to asbestos exposure. He has been queried, by either plaintiffs' or defense attorneys, concerning clinical findings and epidemiologic aspects of asbestos exposure, including quality assurance.

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## To the Editor:

The stated purpose of the article by Gitlin et al (1) on comparing B readers' interpretations of chest radiographs for asbestos-related changes was "to determine if chest radiographic interpretations by physicians retained by attorneys representing persons alleging respiratory changes from occupational exposure to asbestos would be confirmed by independent consultant readers." This is an important objective scientifically and for public policy, and has major legal ramifications. However, because of potential flaws in the design, execution, and analyses of Gitlin and colleagues' study, that were ambiguously reported in their article, the study objective may not have been achieved.

An essential element in the design of this type of study is the process by which films are selected for inclusion in the study. In order for the results to be interpretable and generalizable, films entered into the study must be randomly selected and therefore likely to be representative of the distribution of all similar films, and thus free of bias. In the article by Gitlin et al, the film selection process is described as follows: "Seven groups of films and initial reports, totaling 551 cases, were made available to the authors from several legal sources. The authors were not given the names of the plaintiffs' law firms nor was demographic material provided about the individuals who were examined."

Gitlin and colleagues' article carries no description of the film-selection process used in their study, and it would appear that the authors have no knowledge of this process, since they did not select the films. We are not

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told whether films were selected randomly. We are not told whether the 551 cases used in the study are a sample that is representative of all cases in the "universe" of plaintiff films submitted for litigation purposes. On the basis of the text of the article, it would appear that the authors could not address these issues. In fact, the article implies that the films were selected by defense law firms that have an interest in rebutting the film interpretations of the B readers hired by plaintiffs' counsel. In other words, the films may have been selected by parties that stood to benefit by biasing the outcome of the study. Hence, it is possible, if not likely, that the films included in this study were selected because they represent the worst examples of bad readings by plaintiffs' B readers. If the selection of films were to have been done for this reason, the proportion of diagnoses not supported by re-reading would be overestimated.

The criteria and process for selection of the 7 consultant B readers are not described. The problem in relation to selection of the consultant readers is similar to the problem outlined above for film selection. Who selected the consultant B readers? Were they selected by the authors, or were they selected by the defense law firms that funded the study? Were the consultant B readers a representative sample of all B readers, or of all B readers that provide service to defense law firms? While there may be biased B readers hired by plaintiffs' lawyers, the same problems with bias may theoretically occur with B readers hired by defense lawyers. Biased selection of the consultant B readers could lead to bias in the results of the study. Without knowledge of the criteria and process used for selection of the consultant B readers, the results of the study suffer from unknown bias, and are not interpretable.

The stated objective of the study is one-sided, since the study sought only to assess the validity and potential bias of B readers hired by plaintiffs' lawyers. The research question should be posed in a symmetric manner: Are B readers used in the context of asbestos litigation biased, and are B readings performed in this context biased? This would apply to B readers hired by plaintiffs' lawyers and B readers hired by defense lawyers. Because the study examines only one half of the question, readers of the study may mistakenly assume that B readers hired by defense lawyers are inherently more objective and less biased than B readers hired by plaintiffs' lawyers. Although there are reputable B readers who provide service to defense and/or plaintiffs' lawyers, there is no scientific foundation for the assumption that one set of B readers is

more or less biased than the other—no published studies specifically examine the validity or biases of B readers hired by defense lawyers as compared to B readers hired by plaintiffs' lawyers.

The last paragraph of Gitlin and colleagues' article, immediately before the concluding section of the article, states the following:

"In addition to the present study, the authors reviewed the world literature on chest X-ray studies of lung changes related to mineral dust retention in various worker populations (22-37). These reports discussed studies in several countries of worker populations exposed to asbestos and other mineral dusts. Most of the studies used the ILO 80 system as a means of recording their findings. Allowing for variations in technique, the studies cited involved interpretation of radiographs by more than one expert reader with aggregate results reported. In no instance did the conclusions agree with the high level of positivity (1/0 or higher on the ILO scale for small opacities) reported by the initial readers in the current study. The proportion of parenchymal abnormality—small opacity profusion ratings of 1/0 and higher—reported by the initial readers were significantly higher than those recorded by the consultant readers. The findings in the literature, which apply to asbestos worker groups and those exposed to other mineral dusts, support the results of the consultants' interpretations in this study rather than the high levels of positivity reported by the initial readers."

The conclusion stated here is without foundation, and fails to account for selection of cases that occurs in the context of litigation. While in any given worker cohort the prevalence of radiographic abnormalities may be high, medium, or low, one would anticipate that only those workers believed to have radiographic abnormalities would file claims for compensation. Hence, the prevalence of radiographic abnormalities among persons who file claims would be expected to be at or near 100%, regardless of the prevalence of such abnormalities in the larger population from which these persons were drawn.

We share the concern of Gitlin and colleagues that various biases may occur with B reading in the context of asbestos litigation. However, in the study they conducted, neither the process for selecting films nor that for selecting consultant B readers was defined, and both may have suffered from unknown selection biases. For these reasons, and without further information, no valid scientific conclusions can be drawn from Gitlin and colleagues' investigation.



**IN THE UNITED STATES BANKRUPTCY COURT  
FOR THE DISTRICT OF DELAWARE**

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**IN RE:**

**OWENS CORNING, et al.,**

**Debtors.**

**CHAPTER 11  
Case Nos. 00-3837 to 3854 (JFK)  
(Jointly Administered)**

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**WITNESS:  
Dr. Joseph Gitlin**

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Washington, DC**

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In re:

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Debtors.

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Case Nos. 00-3837 to 3854 (JPF)

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DEPOSITION OF:

Dr. Joseph N. Gitlin

15

DATE:

December 17, 2004

16

LOCATION:

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LEAD:

Caplin & Drysdale

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U.S. Bankruptcy Court  
In Re: Owens Corning

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